LACTATED RINGERS - sodium chloride, sodium lactate, potassium chloride and calcium chloride irrigant

Baxter Healthcare Corporation

DESCRIPTION

Lactated Ringer's Irrigation is a sterile, nonpyrogenic, isotonic solution in a single dose ARTHROMATIC plastic container for use as an arthroscopic irrigating solution. Each liter contains 6.0 g Sodium Chloride, USP, (NaCl), 3.1 g Sodium Lactate (C₃H₅NaO₃), 300 mg Potassium Chloride, USP, (KCl), and 200 mg Calcium Chloride, USP, (CaCl₂•2H₂O). pH 6.5 (6.0 to 7.5). Milliequivalents per liter: Sodium - 130, Potassium - 4, Calcium - 3, Chloride - 109, Lactate - 28. Osmolarity 273 mOsmol/L (calc.). No antimicrobial agent has been added.

The ARTHROMATIC plastic container is fabricated from a specially formulated polyvinyl chloride (PL 146 Plastic). The amount of water that can permeate from inside the container into the overwrap is insufficient to affect the solution significantly. Solutions in contact with the plastic container can leach out certain of its chemical components in very small amounts within the expiration period, e.g., di-2-ethylhexylphthalate (DEHP), up to 5 parts per million. However, the safety of the plastic has been confirmed in tests in animals according to USP biological tests for plastic containers as well as by tissue culture toxicity studies.

CLINICAL PHARMACOLOGY

Lactated Ringer's Irrigation is useful as an irrigating fluid for body joints because it approximates the electrolyte composition of synovial fluid, and provides a transparent fluid medium with optical properties suitable for good visualization of the interior joint surface during endoscopic examination. During arthroscopic surgical procedures, the solution acts as a lavage for removing blood, tissue fragments, and bone fragments.

INDICATIONS AND USAGE

Lactated Ringer's Irrigation is indicated for use as an arthroscopic irrigating fluid with endoscopic instruments during arthroscopic procedures requiring distension and irrigation of the knee, shoulder, elbow, or other bone joints.

CONTRAINDICATIONS

None known.

WARNINGS

Not for injection.

Because fluids used to irrigate joints may be absorbed into the general circulation, solutions containing sodium ion should be used with great care in patients with congestive heart failure, severe renal insufficiency, and in clinical states in which there exists edema with sodium retention.

The contents of an opened container should be used promptly to minimize the possibility of bacterial growth or pyrogen formation. Discard the unused portion of irrigating solution since no antimicrobial agent has been added.

PRECAUTIONS

Because some of the fluid used to irrigate joints may be absorbed, caution must be exercised in the volume of irrigating fluid used especially with solutions containing the sodium ion in patients receiving corticosteroids or corticotropin.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

Do not administer unless the solution is clear and the seal is intact.

ADVERSE REACTIONS

None known.

DOSAGE AND ADMINISTRATION

The volume of solution needed will vary with the nature and duration of the arthroscopic procedure.

If desired, warm in overwrap to near body temperature in a water bath or oven heated to not more than 45° C.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.

HOW SUPPLIED

Lactated Ringer's Irrigation in ARTHROMATIC Plastic Container is available as follows:

2B7487	3000 mL	NDC 0338-0137-27
2B7489	5000 mL	NDC 0338-0137-29

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25° C); brief exposure up to 40° C does not adversely affect the product.

DIRECTIONS FOR USE

Tear overwrap down side at slit and remove solution container. Some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Check for minute leaks by squeezing bag firmly. If leaks are found, discard solution as sterility may be impaired. Use Aseptic Technique.

- 1. Suspend container using hanger hole.
- 2. Remove protector from outlet port.
- 3. Attach irrigation set. Refer to complete directions accompanying set.

Baxter Healthcare Corporation

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PACKAGE LABEL - PRINCIPAL DISPLAY PANEL Container Label

NOT FOR INJECTION

4500 5000 mL

2B7489

NDC 0338-0137-29

4000

Lactated Ringers IRRIGATION

3500

3000

EACH 100 mL CONTAINS 600 mg SODIUM CHLORIDE USP 310 mg Sodium Lactate 30 mg Potassium Chloride USP 20 mg CALCIUM CHLORIDE USP NO ANTIMICROBIAL AGENT HAS BEEN ADDED pH 6.5 (6.0 to 7.5) mEg/L Sodium 130 Potassium 4 CALCIUM 3 CHLORIDE 109 LACTATE 28 OSMOLARITY 273 mOsmol/L (CALC) STERILE NONPYROGENIC SINGLE DOSE CONTAINER

NOT USE UNLESS SOLUTION CLEAR DISCARD UNUSED PORTION

2000

SQUEEZE AND INSPECT INNER BAG WHICH CAUTIONS MAINTAINS PRODUCT STERILITY DISCARD IF LEAKS ARE FOUND RX ONLY STORE UNIT IN MOISTURE BARRIER OVERWRAP AT ROOM TEMPERATURE (25°C) UNTIL READY TO USE AVOID EXCESSIVE HEAT SEE INSERT

1500

Lactated Ringers IRRIGATION

1000

ARTHROMATIC CONTAINER

PL 146 PLASTIC



BAXTER ARTHROMATIC AND PL 146 ARE TRADEMARKS OF BAXTER INTERNATIONAL INC

FOR PRODUCT INFORMATION 1-800-933-0303

500

MADE IN USA

NOT FOR INJECTION 5000 mL 2B7489 NDC 0338-0137-29 **Lactated Ringers** IRRIGATION

EACH 100 mL CONTAINS 600 mg SODIUM CHLORIDE USP 310 mg SODIUM LACTATE 30 mg POTASSIUM CHLORIDE

USP 20 mg CALCIUM CHLORIDE USP NO ANTIMICROBIAL

AGENT HAS BEEN ADDED pH 6.5 (6.0 to 7.5)

mEq/L SODIUM 130 POTASSIUM 4 CALCIUM 3

CHLORIDE 109 LACTATE 28 OSMOLARITY 273 mOsmol/L

(CALC) STERILE NONPYROGENIC SINGLE DOSE

CONTAINER

DO NOT USE UNLESS SOLUTION IS CLEAR

DISCARD UNUSED PORTION

CAUTIONS SQUEEZE AND INSPECT INNER BAG WHICH

MAINTAINS PRODUCT STERILITY DISCARD IF LEAKS ARE

FOUND **RX ONLY** STORE UNIT IN MOISTURE BARRIER

OVERWRAP AT ROOM TEMPERATURE (25°C) UNTIL READY TO

USE AVOID EXCESSIVE HEAT SEE INSERT

Lactated Ringers

IRRIGATION

ARTHROMATIC CONTAINER

PL 146 PLASTIC

Raytor

BAXTER HEALTHCARE CORPORATION

DEERFIELD IL 60015 USA

MADE IN USA

BAXTER ARTHROMATIC AND

PL 146 ARE TRADEMARKS OF

BAXTER INTERNATIONAL INC

FOR PRODUCT INFORMATION

1-800-933-0303

Carton Label

LACTATED RINGER'S IRRIGATION

SECONDARY BAR CODE

(17) YYMM00 (10) XXXXX

PRIMARY BAR CODE

(01) 50303380137294

2B7489

ARTHROMATIC CONT 2-5000ML

LOT XXXXX EXP XXXXX

LACTATED RINGER'S IRRIGATION ARTHROMATIC CONT 2-5000ML SECONDARY BAR CODE (17) YYMM00 (10) XXXXX PRIMARY BAR CODE (01) 50303380137294 LOT XXXXX EXP XXXXX 2B7489